REMARKS

The Examiner noted in the Office Action mailed on November 3, 2004 that the claims filed on July 9, 2004 did not comply with the requirements of 37 C.F.R. §1.173. Nevertheless, the Examiner rejected the amended claims under 35 U.S.C. § 112. Accordingly, Applicants interpret the Office Action as responsive to the Claims as amended on July 9, 2004. For the record, Applicants have attached herewith as Appendix A a listing of the claims as amended on July 9, 2004 in compliance with the requirements of 37 C.F.R. §1.173, entitled "SUBSTITUTE LISTING OF CLAIMS FILED ON JULY 9, 2004."

Claims 1-24 are pending in the above-identified application. Claims 15, 17, 19, and 20 have been amended. Support for these amendments can be found in the specification of the issued patent at column 4, lines 19-22, "after premixing of the medicines with the swallowing-assistive drink, the obtained mixture (liquid) may be poured into the mouth and swallowed." (Emphasis added.) Accordingly, no new matter has been introduced by way of this amendment. Reconsideration of the application in view of these amendments and the comments below is respectfully requested.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejected Claims 1-14 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. In particular, it is alleged that the specification fails to provide support for the limitation "packaged in a prepared form in the absence of medication" in Claims 1 and 6, and the limitation "prepared form" in Claims 11 and 13.

To satisfy the written description requirement, a patent application must describe the invention in sufficient detail that one of skill in the relevant art could conclude that the inventor was in possession of the claimed invention at the time the application was filed. *See Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). There is no *in haec verba* requirement, provided newly added claim limitations are supported in the specification through express, implicit, or inherent disclosure. M.P.E.P. § 2163. The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention now claimed. M.P.E.P. § 2163.02 (citing *Vas-Cath, Inc.* at 1563-64.)

Applicants respectfully submit that the limitations, "packaged in a prepared form in the absence of medication" in Claims 1 and 6 and "prepared form" in Claims 11 and 13 are fully supported by the specification, for example, at col. 3, lines 35-39, "with excellent stability, it is easy to carry [the swallowing assistive drink] if it is filled in a small container or the like, being convenient when patients go out." Thus, the specification conveys with reasonable clarity that Applicants possessed the claimed swallowing-assistive drink in a prepared form as the specification clearly suggests that given the excellent stability of the claimed swallowing-assistive drink, the product could be packaged for the end-user in a prepared form. Accordingly, Applicants were in possession of the claimed swallowing-assistive drink in a prepared form at the time the application was filed. Note that the convenience and functionality of a pre-packaged, prepared product are important distinctions of the present invention.

In view of the foregoing, Applicants respectfully submit that Claims 1-14 comply with the written description requirement of 35 U.S.C. § 112. Applicants respectfully request withdrawal of this rejection.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claims 15-20 and 22 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. In particular, the Examiner asserts that the use of the phrase "swallowing the combination in conjunction with the combining step" is unclear because the combining step is to make the "combination" and then the "combination" is being swallowed.

Applicants have amended Claims 15, 17, 19, and 20 to clarify that the combination is being swallowed after the combining step. (Claim 22 does not contain the language in question.) Support for these amendments can be found in the specification of the issued patent at column 4, lines 19-22, "after premixing of the medicines with the swallowing-assistive drink, the obtained mixture (liquid) may be poured into the mouth and swallowed." (Emphasis added.) Applicants submit that amended Claims 15-20 and 22 are definite and recited with particularly under 35 U.S.C. § 112, second paragraph. Accordingly, Applicants respectfully request that the rejection under this section be withdrawn.

Rejection Under 35 U.S.C. § 103

The Examiner rejected Claims 1-24 under 35 U.S.C. § 103(a) as being unpatentable over Speck *et al.*, U.S. Patent No. 5,010,061. Specifically, the Examiner asserts that Speck discloses that drugs, vitamins and contrast agents can be added to guar flour, mixed with water and drunk immediately, one of skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful in assisting an individual in swallowing a drug.

In response to Applicants arguments filed on July 9, 2004, that Claims 1 and 6 are patentable over Speck in view of the product-by-process limitation "packaged in a prepared form in the absence of a medication prior to enwrapping the medicine," the Examiner states that the Applicants have not pointed out support for the amendments made. In addition, the Examiner states that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself.

Similarly, the Examiner states that support was not provided for the amendments to Claims 11 and 13 to include the limitation "in a prepared form." Additionally, the Examiner states that no criticality is seen in the particular limitation because Speck teaches drinkable compositions comprising water and a paste, which form a viscous liquid and a medicine enwrapped in the viscous liquid as claimed in instant claims 1, 2, 6, 7, 21 and 23.

To establish a *prima facie* case of obviousness a three-prong test must be met. First, there must be some suggestion or motivation, either in the references or in the knowledge generally available among those of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success found in the prior art. Third, the prior art reference must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

As a preliminary matter, Applicants again submit that the structural limitations, "packaged in a prepared form in the absence of medication" in Claims 1 and 6 and "prepared form" in Claims 11 and 13 are fully supported by the specification, for example, at col. 3, lines 35-39, "with excellent stability, it is easy to carry [the swallowing assistive drink] if it is filled in a small container or the like, being convenient when patients go out." Thus, it is clear from the specification that Applicants were in possession of the claimed swallowing-assistive drink in a prepared form at the time the application was filed.

Applicants submit that Speck *et al.* fails to establish a *prima facie* case of obviousness because the cited reference does not teach all of the limitations of the claimed invention.

Speck *et al.* discloses guar flour formulations for use as a drug or as a food additive. The purpose of that invention is to allow the patient to drink the guar flour itself. The drug and vitamins are ancillary options only, and there is no suggestion that guar flour can make it easier to take medicine. The formulations disclosed in Speck *et al.* are produced without using additive substances to reduce or delay the swelling ability and can be easily consumed in smaller doses and in a more comfortable way than was known in the prior art.

The claims of the instant invention are directed to a swallowing-assistive drink in a prepared form and methods for taking medication comprising providing a swallowing-assistive drink in a prepared form. Thus, the structural limitation "in a prepared form" is a meaningful feature of the claims, and therefore, must be considered in evaluating the patentability of the claims. The specification of Speck *et al.* repeatedly states that the guar flour formulations disclosed therein must be drunk "rapidly" (col. 4, line 23), "soon after" (col. 4, lines 9-10, 28, and 35), and/or "within 5 minutes" (col. 4, line 17, see also col. 3, lines 30-31 "preferably 0 to 5 minutes after complete mixing"). Thus, Speck *et al.* does not teach guar flour formulations in a prepared form. On the contrary, Speck *et al.* teaches away from guar flour formulations in a prepared form, instead teaching that at room temperature, the formulations remain sufficiently fluid for 5 minutes minutes (col. 3, lines 12-13). A person of ordinary skill in the art would not be motivated to package the disclosed guar flour formulations such that the end-user could carry the formulations in a prepared form, nor would there be a reasonable expectation of success in doing so, given that Speck *et al.* discloses repeatedly that the formulations do not remain drinkable for more than 5 minutes after mixing. Accordingly, Applicants submit that the PTO has failed to establish a *prima facie* case of obviousness because the cited reference teaches away from the claimed invention. Nothing in this reference allows the user to solve the problem solved so well by the present invention: how to assist a patient in swallowing his or her medicine, whatever that medicine may be.

Applicants respectfully submit that the cited reference does not render Claims 1-24 obvious because it does not teach or suggest a swallowing-assistive drink in a prepared form, and thus, does not teach all of the limitations of the claims (or provide any of their benefits). Additionally, there would be no motivation to attempt to package the guar flour formulations

disclosed in Speck *et al.* in a prepared form and there would be no reasonable expectation that such modifications could be made, as evidenced by the fact that Speck *et al.* teaches that the disclosed formulations must be drunk within 5 minutes of mixing. Accordingly, Speck *et al.* cannot support a *prima facie* case of obviousness. Indeed, aside from an incidental and superficial similarity, the two inventions are completely different, and Speck *et al.* in no way address the problem solved by the present invention.

In light of the foregoing, Applicants respectfully submit that Claims 1-24 are not obvious under 35 U.S.C. § 103(a) and hereby request that this rejection be withdrawn.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action have been addressed and that the application is now in condition for allowance. Accordingly, Applicants request the expeditious allowance of the pending claims.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the undersigned to discuss such issues.

Applicants believe that no fees are due. However, please charge any additional fees that are due, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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APPENDIX A

SUBSTITUTE LISTING OF CLAIMS FILED ON JULY 9, 2004

Pursuant to 37 C.F.R. §1.173(d) , matter to be omitted is [bracketed] and matter to be added is underlined.

25. (Once Amended) A swallowing-assistive drink for assisting an individual in swallowing a medication, the swallowing-assistive drink comprising:

water and an adhesive paste which form a viscous liquid having a viscosity in the range of from 1,000-25,000 cP at 20°C; and

a medicine enwrapped in the viscous liquid;

wherein said swallowing-assistive drink has been packaged in a prepared form in the absence of a medication prior to enwrapping the medicine.

26. (Original) The swallowing-assistive drink of claim 1 wherein the adhesive paste is at least one selected from the group consisting of agar, carrageenan, gellan gum, furcellaran, gelatin, pectin, curdlan, locust bean gum, tara gum, guar gum, xanthan gum, arginic acid, arginic acid salt, azotobacter vinelandi gum, cassia gum, psyllium seed gum, tamarind gum, CMCNa, CMCCa, whey protein starch and modified starch.

27. (Original) The swallowing-assistive drink of claim 1 wherein the swallowing-assistive drink contains in the range of from 0.1-5.0 wt % adhesive paste and in the range of from 80.0-99.9 wt % water.

28. (Original) The swallowing-assistive drink of claim 1 wherein the medicine is at least one of a tablet, a capsule, a granule, and powder.

29. (Original) The swallowing-assistive drink of claim 1 wherein the medicine is a mixture of solid formulations and at least one of granules and powder.

30. (Twice Amended) A swallowing-assistive drink for helping an individual swallow a medication, the swallowing-assistive drink comprising:

water and an adhesive paste which forms a gelatinoid having a gel strength in the range of from 10-100 g/cm^2 at 20°C; and

a medicine enwrapped in the gelatinoid;

wherein said swallowing-assistive drink is packaged in a prepared form in the absence of a medication prior to enwrapping the medicine.

31. (Original) The swallowing-assistive drink of claim 6 wherein the adhesive paste is at least one selected from the group consisting of agar, carrageenan, gellan gum, furcellaran, gelatin, pectin, curdlan, locust bean gum, tara gum, guar gum, xanthan gum, arginic acid, arginic acid salt, azotobacter vinelandi gum, cassia gum, psyllium seed gum, tamarind gum, CMCNa, CMCCa, whey protein starch and modified starch.

32. (Original) The swallowing-assistive drink of claim 6 wherein the swallowing-assistive drink contains in the range of from 0.1-5.0 wt % adhesive paste and in the range of from 80.0-99.9 wt % water.

33. (Original) The swallowing-assistive drink of claim 6 wherein the medicine is at least one of a tablet, a capsule, a granule, and powder.

34. (Original) The swallowing-assistive drink of claim 6 wherein the medicine is a mixture of solid formulations and at least one of granules and powder.

35. (Once Amended) A method for assisting an individual in taking a medicine by swallowing the medicine, the method comprising the steps of:

(a) providing a swallowing-assistive drink in a prepared form containing water and an adhesive paste which forms a viscous liquid having a viscosity in the range of from 1,000-25,000 cP at 20°C; and

(b) enwrapping the medicine in the viscous liquid.

36. (Original) The method of claim 11 wherein step (b) comprises enwrapping at least one of a tablet, a capsule, a granule, and powder in the viscous liquid.

37. (Twice Amended) A method for assisting an individual in taking a medicine by swallowing the medicine, the method comprising the steps of:

(a) providing a swallowing-assistive drink in a prepared form containing water and an adhesive paste which forms a gelatinoid having a gel strength in the range of from 10-100 g/cm^2 at 20°C; and

(b) enwrapping the medicine in the gelatinoid.

38. (Original) The method of claim 13 wherein step (b) comprises enwrapping at least one of a tablet, a capsule, a granule, and powder in the gelatinoid.

39. (Once Amended) A method for taking a medication, comprising the steps of:

providing a viscous swallowing-assistive material in prepared form, wherein the swallowing-assistive material has a viscosity of 1,000-25,000 cP at 20°C;

combining the swallowing-assistive material with a medicine;

wherein the medicine is enwrapped within the swallowing-assistive material; and

swallowing the combination [immediately after] in conjunction with the combining step.

40. (Previously Presented) The method of Claim 15 wherein the medicine is at least one of a tablet, a capsule, a granule, and powder.

41. (Once Amended) A method for taking a medication, comprising the steps of:

providing a viscous swallowing-assistive material in prepared form, wherein the swallowing-assistive material has a gel strength of 10-100 g/cm^2 at 20°C;

combining the swallowing-assistive material with a medicine;

wherein the medicine is enwrapped within the swallowing-assistive material; and

swallowing the combination [immediately after] in conjunction with the combining step.

42. (Previously Presented) The method of Claim 17 wherein the medicine is at least one of a tablet, a capsule, a granule, and powder.

43. (Once Amended) A method for swallowing a solid material, comprising the steps of:

providing a viscous swallowing-assistive material in prepared form, wherein the swallowing-assistive material has a viscosity of 1,000-25,000 cP at 20°C;

combining the swallowing-assistive material with the solid material;

wherein the solid material is enwrapped within the swallowing-assistive material; and

swallowing the combination [immediately after] in conjunction with the combining step.

44. (Once Amended) A method for swallowing a solid material, comprising the steps of:

providing a viscous swallowing-assistive material in prepared form, wherein the swallowing-assistive material has a gel strength of 10-100 g/cm^2 at 20°C;

combining the swallowing-assistive material with the solid material;

wherein the solid material is enwrapped within the swallowing-assistive material; and

swallowing the combination [immediately after] in conjunction with the combining step.

45. (Previously Presented) A swallowing-assistive material suitable for combining with a medicine, comprising:

water; and

one or more of the following viscosity building agents: agar, carrageenan, gellan gum, furcellaran, gelatin, pectin, curdlan, locust bean gum, tara gum, guar gum, xanthan gum, arginic acid, arginic acid salt, azotobacter vinelandi gum, cassia gum, psyllium seed gum, tamarind gum, CMCNa, CMCCa, whey protein starch and modified starch;

wherein said swallowing-assistive material is in a prepared form uncombined with a medicine, and comprises a viscous liquid having a viscosity in the range of from 1,000-25,000 cP at 20°C.

46. (Previously Presented) The swallowing-assistive material of claim 19 wherein the swallowing-assistive material comprises 0.1-5.0 wt % viscosity building agent and 80.0-99.9 wt % water.

47. (Previously Presented) A swallowing-assistive material suitable for combining with a medicine, comprising:

water; and

one or more of the following viscosity building agents: agar, carrageenan, gellan gum, furcellaran, gelatin, pectin, curdlan, locust bean gum, tara gum, guar gum, xanthan gum, arginic acid, arginic acid salt, azotobacter vinelandi gum, cassia gum, psyllium seed gum, tamarind gum, CMCNa, CMCCa, whey protein starch and modified starch;

wherein said swallowing-assistive material is in a prepared form uncombined with medicine and comprises a viscous liquid having a gel strength of 10-100 g/cm^2 at 20°C.

48. (Previously Presented) The swallowing-assistive material of claim 21 wherein the swallowing-assistive material comprises 0.1-5.0 wt % viscosity building agent and 80.0-99.9 wt % water.